| OF |

AD
A071407

END
-DATE
FILMED
9-79
DDC

AD A071407

THE DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS

FOR THE EARLY FUNCTIONAL RESTORATION OF THE INJURED HAND

LEVEL

Annual Report

November 1978

(for the period 1 September 1977 to 30 November 1978

by

James M. Hunter, M. D.
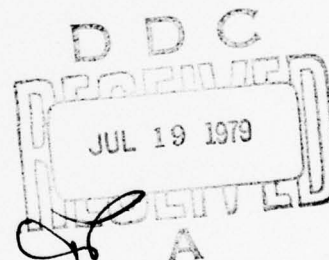John J. Konikoff, Ph. D.
Glenn A. Mackin, B. A.

Nov 78

38p.

Supported by

US Army Medical Research and Development Command
Fort Detrick, Frederick, Maryland 21701

Contract No. DAMD 17-76-C-6036

Jefferson Medical College
Philadelphia, Pennsylvania 19107

DDC
JUL 19 1979
A

Approved for public release; distribution unlimited

The findings in this report are not to be construed as
an official Department of the Army position unless so
designated by other authorized documents.

3S762772A815

79 07 16 027

The primary goal of this research effort is to produce an active hand tendon prosthesis at the earliest possible date. During the past year several separate important lines of investigation have resulted in the convergence toward the desired end. These include:

A) Continued improvements to the design of a sintered titanium plug for permament distal attachment to bone.

B) An alternate distal attachment approach has been evaluated based on the use of a specially-designed metallic end piece which is secured to the distal phalanx by a screw.

C) Biocompatability of the tendon shaft material has been favorably resolved.

D) Early results obtained from tendon shaft and distal attachment to bone indicate that the strength of the latest design shaft is compatible with the natural in vivo system.

E) A loop design has shown great promise as a successful means for proximal attachment.

F) The research involving flexor tendon nutrition and biomechanics has generated valuable practical information defining surgical indications for the implant, as well as the surrounding anatomic structure necessary for its function.

G) Procurement, checkout, and operational readiness of the data acquisition system has been accomplished.

Details of these achievements are described below:

A. The work performed by Dr. Rostoker at the University of Illinois (Chicago campus) under subcontract to us has proceeded well. The attachment of Dacron-Kevlar tapes and the new Dacron braids to sintered titanium end pieces has been refined to permit an increase in tensile strength so that

the prosthetic design is now about equivalent to the natural tendon-bone strength. The attached paper, Enclosure A, entitled "Finger Fixation of an Active Gliding Tendon," discusses the design, manufacture, and testing of a distal attachment assembly which will permit permanent ingrowth of bone into the interstices of the sintered titanium plug.

B. An independent but related study has been completed recently which will aid in our quest for an effective alternate distal attachment technique. Made in conjunction with the Holter-Hausner International Co., the Hunter-Hausner Tendon Implant (H.H.T.I.) represents definite progress over the gliding implant now manufactured by the Extracorporeal Corp. for military and civilian surgeons. Development costs were covered by Holter-Hausner. The H.H.T.I. consists of a prefabricated, high-carbon steel plate with bone fixation points that is attached to a Bally Ribbon Mill special specification Dacron tape by a new heat-mold technique. Using a screw of a similar metal, the distal end of this gliding implant is simply and securely affixed to bone. It should be emphasized that the distal end of the H.H.T.I. is significantly improved over all previous designs of gliding tendon prostheses. It was approved this year for clinical evaluation by the Federal Food and Drug Administration. Bone fixation strengths approach normal tendon attachment requirements. The device is being studied in the chimpanzee primate model and has been made available to a selected group of hand surgeons for evaluation. Enclosure B is a drawing of the H.H.T.I.

C. In our search for a stronger material to serve as the main structural element of the artificial tendon, the major choices of materials have been stainless steel braid and ribbon, polyester fiber (Dacron), and aramic fiber (Kevlar). The stainless steel material was eliminated due to problems with tissue interaction. (See our reports for 1973, 1974, and 1975.)

However, the decision to select Dacron or Kevlar was a perplexing one.
In 1975, in order to assist in this judgement, implant studies were begun
wherein specially woven Dacron and Kevlar tapes were implanted side by side
into the soft tissue and bone structures of a large dog. The dog was kept on
a carefully supervised diet and functional athletic program. During the past
year, under the direction of William R. Rapp, D.V.M., Consulting Pathologist,
the animal was sacrificed and histological studies were conducted. Complete
organ samples were processed. The only local response to Kevlar and Dacron
implants in the dog after two years was a minimal fibrous tissue reaction.
No difference between the two types of implants was detected by necropsy
or histopathology examination. The necropsy report stated, "There were no
systematic effects manifested by either gross or histomorphologic change."
Hence it appeared, on the basis of one study, that the carcinogenic activity
of Kevlar may have been overstated. In discussions with the DuPont Co.,
manufacturers of Kevlar, it was learned that the manufacturing process had been
revised to replace potentially carcinogenic solvents with materials which
were biocompatible. However, with the receipt of a new high strength Dacron,
the need for Kevlar has been reduced or completely eliminated. Thus, no
toxicity or carcinogenicity problems will require resolution.

D., E. Based upon the studies conducted at the Philadelphia College
of Testiles and Science (PCT&S) of the mechanical properties of the tendon,
fibers, and textile structure, selection of the candidate fiber and the
geometry for the artificial tendon shaft have been made. Figure 1 shows
the new soft-loop prosthesis, the hard-loop prosthesis and the passive-tendon
prosthesis. A close-up view of the soft-loop prosthesis and the titanium
plug with the tendon shaft insertion is shown in Figure 2. The tendon shaft
is a braided structure made of high tenacity polyester yarns. The combination

of a braid geometry with the high tenacity yarn provides the stability and strength required for a tendon prosthesis. The soft loops will enable the tendon prosthesis to absorb impact energy generated by rapid muscle contraction. This will minimize the common mode of failure at the attachments. The loop, especially at the proximal end, should also facilitate surgical operations such as the adjustment of proper tension on the artificial tendon. The distal end of the tendon shaft can be inserted into a sintered titanium plug. Dr. Rostoker of the University of Illinois has found that the braided tendon shaft was easier than the flat woven tape to insert into the central opening of the titanium plug. However, elongation from braid design may limit the attachment.

A few of the double-loop tendon prostheses have been dip-coated with Silastic® by Mr. John Hausner of the Holter-Hausner International Co. The preliminary tests of these prostheses indicated dip-coating will not be acceptable as a technique for clinical trial. New mold designs will be required for pressure molding of silicone rubber to the Dacron shaft. Preliminary tests also indicate that braid designs will require further study and clinical trial. Figures 3 to 5 show the load-elongation relationship, elastic recovery, and stress relaxation behavior of the tendon prosthesis. The average tensile strength of the shaft is 97 kg at 26% elongation. With 4% extension, which is the working range of the natural tendon, there is almost complete recovery from tensile deformation. The loops stay intact after ten cycles of repeated loading and unloading. The rate of stress relaxation is quite slow, which suggests that low creep can be anticipated. According to Professor Rostoker, the shear strength of the tendon shaft-titanium plug interface cemented together by polymethyl methacrylate reaches the level of 40-45 kg, significantly higher than the requirement of 30 kg.

Preliminary tensile tests have been carried out on the flexor digitorum profundus tendon-bone unit at PCT&S. Based on the limited number of observations (ten specimens from two hands of an adult cadaver), we found that the average breaking load of the tendon-bone units is 35 kg. The strength of the tendon-bone units of each finger differs. For example, the tendon-bone unit of the thumb is about twice as strong as the tendon-bone unit of the little finger. Avulsion was found to be the most common type of tendon failure. A summary of the test results and pictures of a typical specimen and test set-up are presented in Table I and Figures 6 and 7 (pp. 12-14).

F. It is apparent from work now being prepared for publication that areas of the flexor tendon system can be rendered avascular, depending on the location of injury, and that this will have a profound effect on tendon healing. This has a direct relationship to the unpredictable results obtained in certain procedures regardless of surgical treatment or skill. Considerations of microvascular and retinacular anatomy may provide surgeons with the predictive power to opt for immediate prosthesis implantation at the time of injury. In this way an injured soldier would be spared additional reconstructive surgery to correct for attempts at primary tendon repair that were doomed to failure for lack of adequate nutrition or structural support.

A subordinate project now completed involving basic tendon nutrition has generated data of military and civilian significance. The result of these studies describes the nutritional aspect of the tendon and demonstrates that present management of the acute phase may be ineffective due to the absence of sufficient blood supply. Variations in the vascular nutrition system of the tendons are shown which were not previously mapped or understood. These data were derived from a study of one hundred and thirty-five fingers using special injection techniques and transillumination photography.

The paper, entitled, "Vascular Anatomy of Flexor Tendons," Part I, has been accepted for publication in the Journal of Hand Surgery.

The second part of the study, presently under preparation, represents a similar series of fresh cadaver material of various age groups, in which injuries have been created to simulate natural laceration, explosion, and missle trauma.

G. As discussed in our earlier communications to your office, the data acquisition system did not arrive at the Philadelphia College of Textiles and Science until April, 1978, and was not available for preliminary work until May, 1978. The delay resulted from administrative problems concerning the purchase of equipment under the current contract. Procurement was not possible until contract funds were made available, purchase details consummated, and equipment placed at the location of operations. The immediate supervisor in the Textile Research Department of PCT&S is Dr. Frank Ko, Assistant Professor of Textile Engineering. Under the newly-acquired system, preliminary test runs on human cadaver tendons have been conducted. Fresh and selected embalmed cadaver material used in such tests has been generously donated, at no cost, by the Department of Anatomy at Jefferson Medical College.

As noted in paragraph D/E above, we are currently studying the normal human attachment of tendon to bone, and the linear structure of human tendons. It has been confirmed that the basic baseline tensile strength figures for tendon and its attachment are in line with the prosthesis structural data mentioned elsewhere in this report.

During the past year we have conducted preliminary studies of the "pulley system" which promise to shed new light on unanticipated failures following retinacular reconstruction. The condition of the pulley system is critical to the range of motion achieved after tenorraphy and staged tendon

grafting. In the preliminary studies, cadaver hands with intact retinacular systems supporting natural flexor tendons were utilized. Injuries similar to surgical problems were created. It was demonstrated that changing moment arms and decreased motion are directly related to patterns of retinacular removal. In addition to the current practice of surgically preserving or reconstructing the (annular) A2 and A4 pulleys, the importance of the A1 pulley emerged from these studies. Such knowledge, essential to the effective installation of an active tendon implant, provides the foundation for further pulley studies using the H.H.T.I. A preliminary report on pulley mechanics was delivered on 23 October 1978 in Indianapolis before the American Society for Surgeons of the Hand. The study will be published complete or in part during 1979 in Difficult Problems in Hand Surgery (Mosby). A preliminary report on the retinacular pulley system is included with this Annual Report as Enclosure C.

H. Enclsure D, "Photographic Study of an Active Tendon Implant," describes the results of an implant study conducted in a chimpanzee finger. A sintered titanium plug, obtained under the University of Illinois subcontract, was implanted aseptically in the middle of the proximal phalanx of the chimpanzee's right ring finger.

I. Enclosure E is a tabulation of the publications and presentations made during the past contract year on the subject of this study.
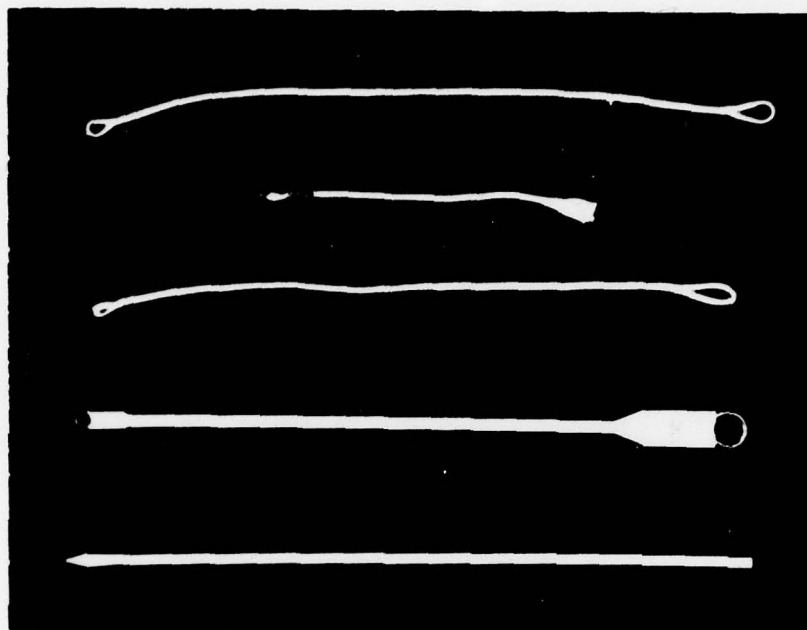
Active
Soft Loop
Tendon
Prothesis

Active
Hard Loop
Tendon
Prothesis

Passive
Tendon
Prothesis

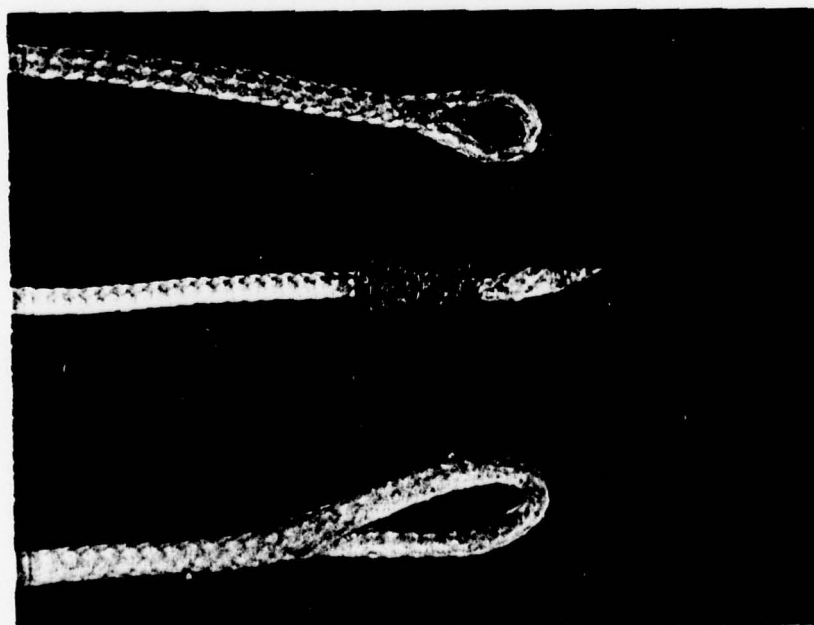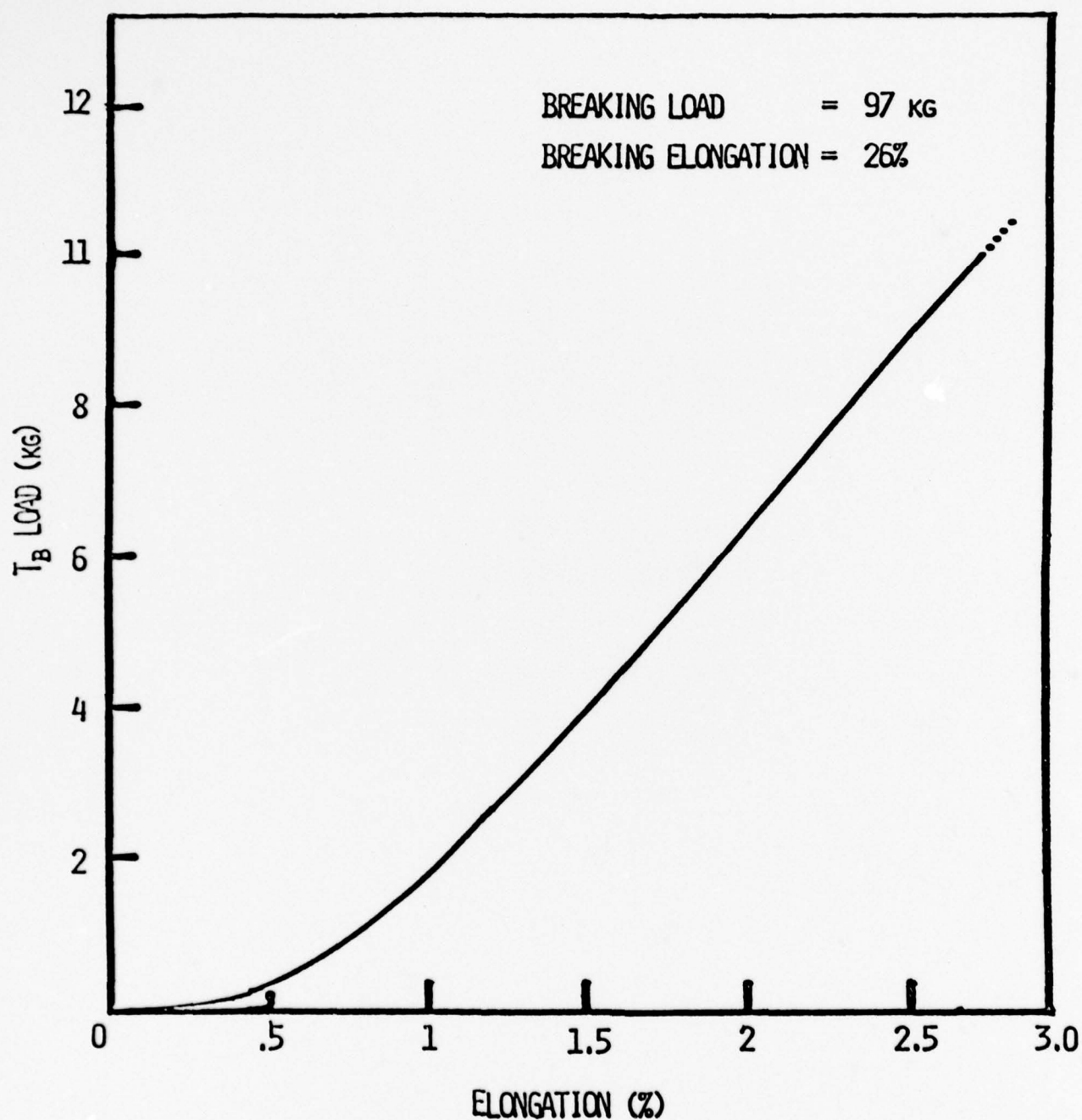Figure 1

Various Tendon Protheses

Figure 2

FIGURE 3

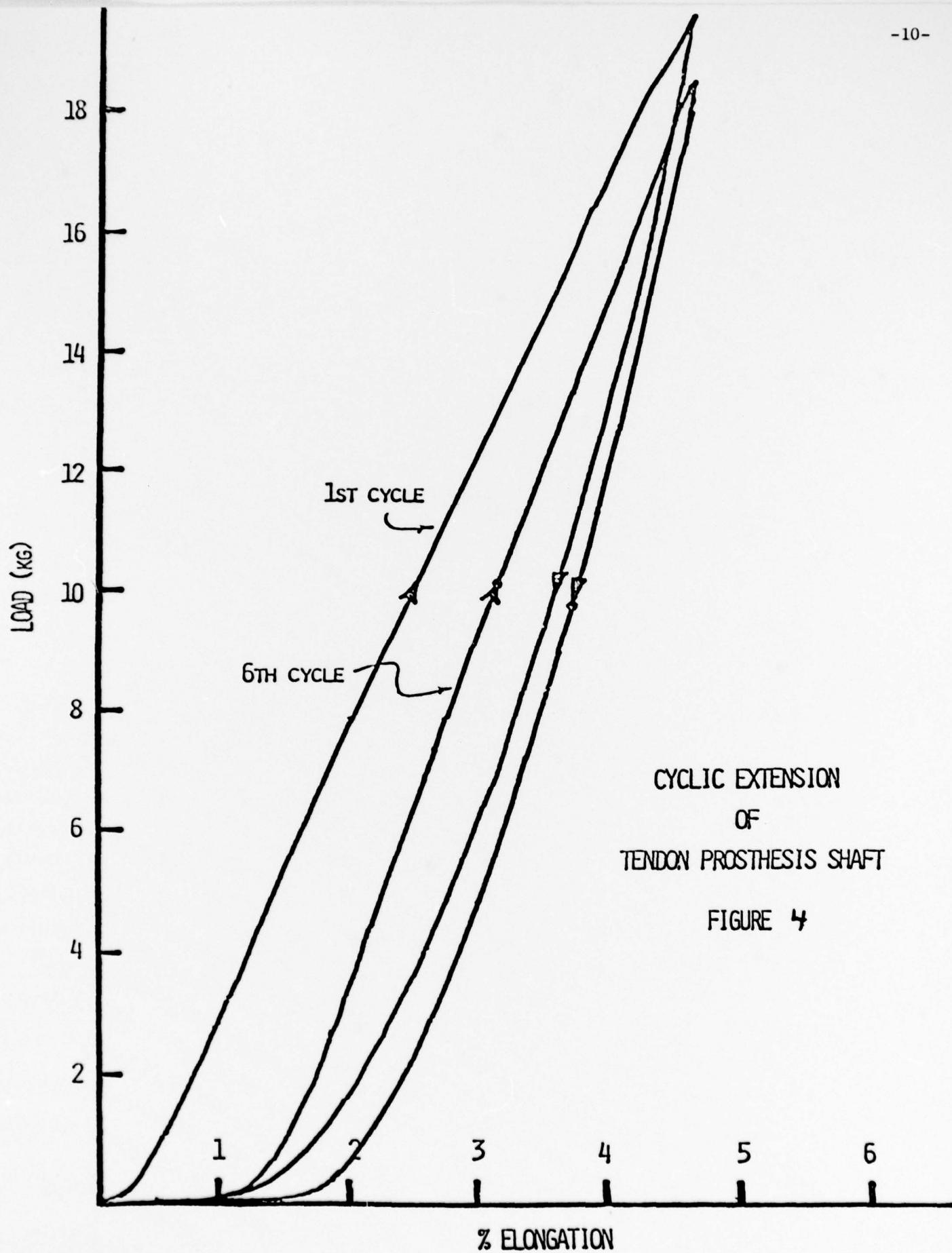LOAD ELONGATION RELATIONSHIP OF TENDON PROSTHESIS SHAFT

CYCLIC EXTENSION
OF
TENDON PROSTHESIS SHAFT

FIGURE 4

FIGURE 5
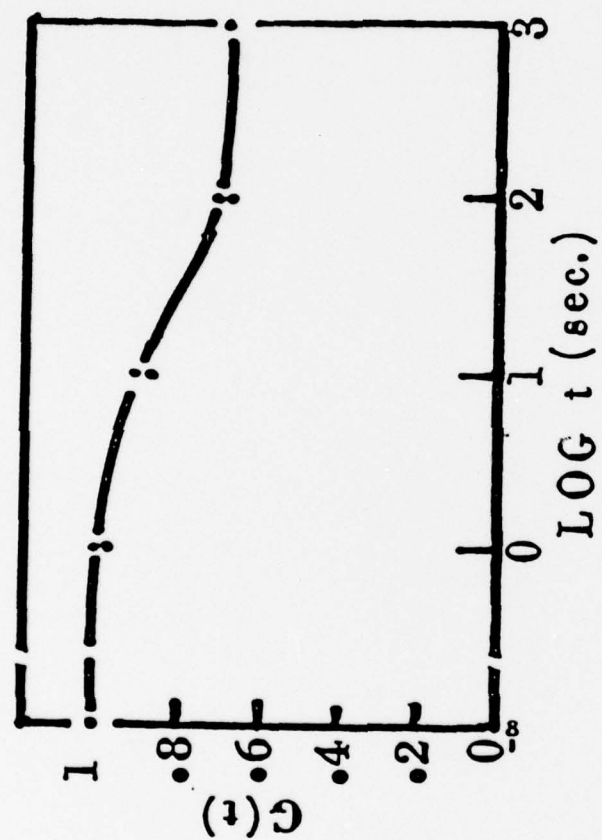
FRACTIONAL STRESS RELAXATION OF
TENDON PROSTHESIS SHAFT

TABLE I

STRENGTH OF FLEXOR DIGITAL PROFUNDUS TENDON-BONE UNITS

| No.	Specimen		Average Width (inch)		Tendon Thickness (inch)	Strength (kg)	Pattern of Rupture
			Tendon	Attachment			
1	72-W-F	Right Ring	.20	.3	.174	38	bone
2		Right Thumb	.20	.3	.175	45	compression
3		Right Little	.20	.3	.150	24	avulsion
4		Right Index	.20	.3	.170	39.5	compression of joint surface
5		Right Long	.25	.3	.185	24	partial rupture of tendon
6		Left Thumb	.20	.3	.155	49	avulsion
7		Left Little	.20	.3	.135	30	complete avulsion
8		Left Index	.20	.3	.140	33.5	avulsion
9		Left Ring	.20	.3	.160	35	avulsion
10		Left Long	.20	.3	.165	29.5	avulsion
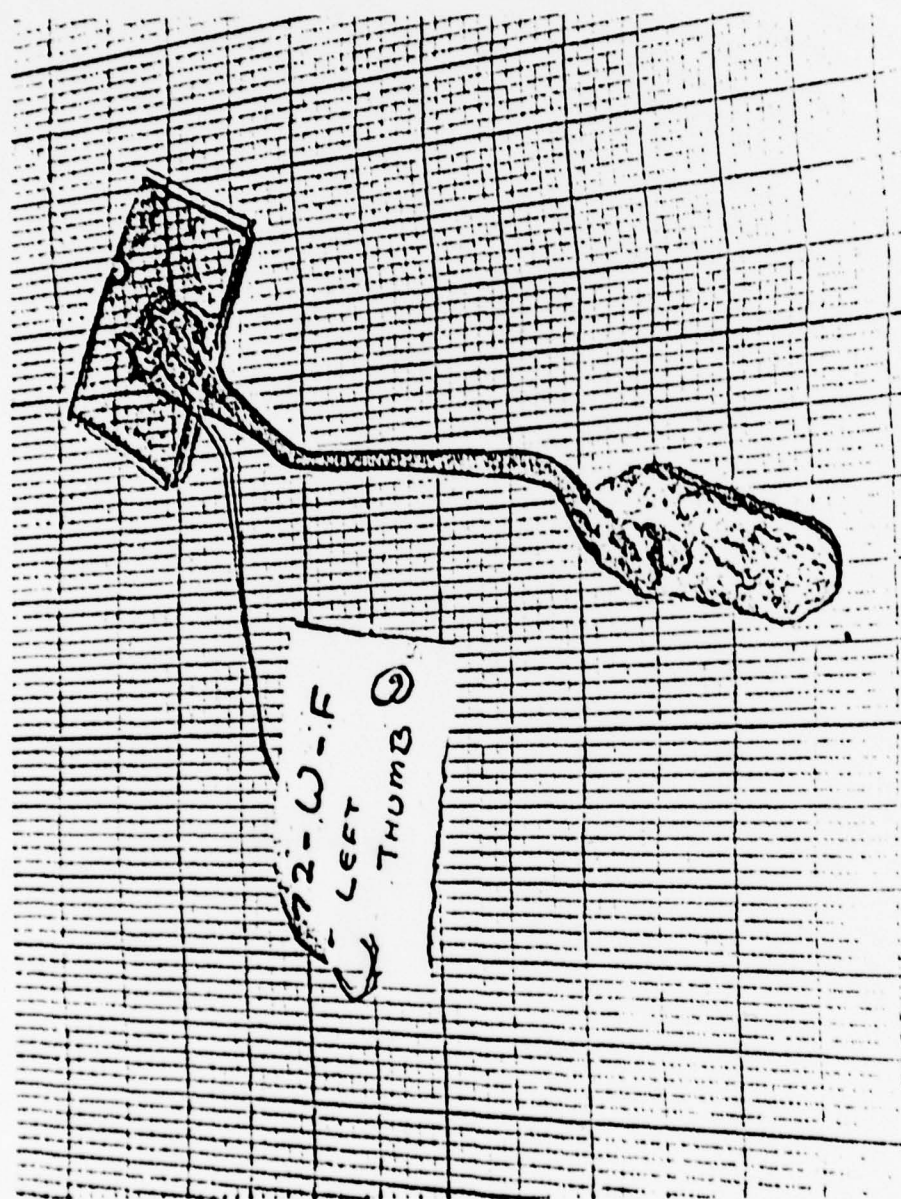
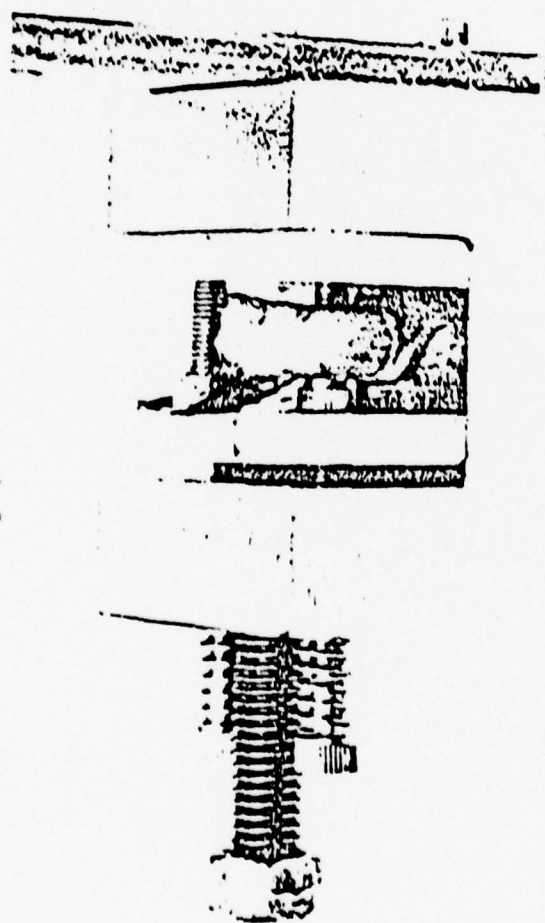Figure 6: A typical tendon-bone unit after avulsion

Figure 7: Test fixture for the tendon-bone unit

FINGER FIXATION OF AN ACTIVE GLIDING TENDON

by

W. Rostoker
Department of Materials Engineering
University of Illinois at Chicago Circle
Chicago, Illinois

The problem is to convert a successful passive gliding tendon into a functional active gliding tendon prosthesis by providing for load-bearing fixation at both extremities. This task deals with fixation to the second phalanx of the finger which, although less than ideal, offers more bone site to work with.

It has been proposed to use bone ingrowth into a porous, inert material as the basis for fixation. There is a specific material which can accomplish this and is amenable to fabrication into the small sizes and shapes appropriate to the intended host bone. This material is molded from fine, titanium wire which has been kinked to a sinusoidal configuration and cut to short lengths. The product when molded and sintered for bonding possesses about 50% void made up to interconnecting channels whose inscribed diameters are about 0.25 mm. The material in various manufactured shapes for various implanted applications has nearly ten years of animal implantation experimentation and human implant experiences some of which now extend beyond three years. In no case has there been an indication of non-biocompatability. In fact vascularized calcified tissue can be seen to begin invasion of the pore zones in less than three weeks.

The fixation scheme involves an assembly or composite whose components are:

(a) a right cylinder of porous titanium which is 4 mm diameter by about 8 mm long with a center hole of 1.5 mm diameter.

(b) a hollow weave Dacron cord which can be threaded into the
     center hole of (a) and which when coated with silicone rubber
     serves as the tendon.

(c) an acrylic cement formulated by readjustment of the powder to
     liquid ratio of bone cement.

(d) a tack-shaped titanium pin which forces the cord, wetted with
     cement, against the wall of the porous titanium cylinder.

The assembly involves fraying the end of the cord, preplacing the
cement on the inside wall of the porous cylinder, threading the cord into
the hole, spreading the frayed ends against the back face of the cylinder,
and forcing the pin into the sleeve zone of the cord so that it expands the
cord against the wall of the cylinder and the cement. The tack-head creates
a second face for adhesion on the back. The mix cures in less than 24 hours.

Such assemblies have been subjected to pull-out tests in simple tension
at room temperature using a micro-tensile-testing machine with special
grips which do not damage the porous material. By testing a sample batch of
ten cord-plug assemblies we have established a mean breaking force of
103.7 lbs. with a standard deviation of ±6.4 lbs. This seems to be a
satisfactory level of strength for the application.

We have proceeded beyond that point to evaluate the resistance of the
assembly to a fluctuating or fatigue stress situation which is a condition
much more severe on any material. In these tests the plug fixation is
applied to both ends of the cord and the whole is immersed in 37°C circulating
physiological solution. Drop weight forces of 40 lbs. are applied at a rate
of about one per second.

Two specimens have survived 100,00 cycles under these conditions.
Others have failed because the porous cylinder mushroomed and separated from
the cord. At this point it is necessary to revise the design of the colletts
which hold the plugs so that they will not distort and thereby damage the
adhesive bond. They will then also replicate the structural condition
associated with the bone embeddment more appropriately.

We believe that the distal fixation system is suitable for trial
implantation. It should also be stated that the implanting tools are
prepared and that even the design of an extractor is prepared if that were
necessary.

FABRICATION OF MODIFIED POROUS METAL FIXATION SYSTEM

## UTILIZING THE TUBULAR CHARACTER OF DACRON TENDON CORD

Technique:

1. Dacron is guided through fiber metal cylinder.

2. A very viscous blend of bone cement is applied to the inner Dacron core.

3. The rivit is pressed into the core in a split die.

4. Assembly cures before testing. (48 hour minimum)

.74 mm

1.8 mm

Sand Blasted Rivit (Ti-64)

4.0 mm

Fiber Metal Cylinder (2.0 mm in diam.)

8.0 mm

DACRON
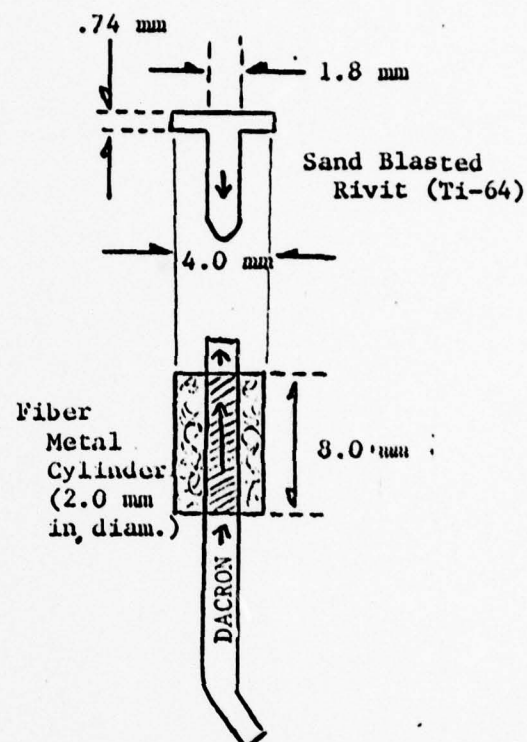
Holter - Hausner International

THE PASSIVE TENDON IMPLANT
(Hunter-Hausner Design)
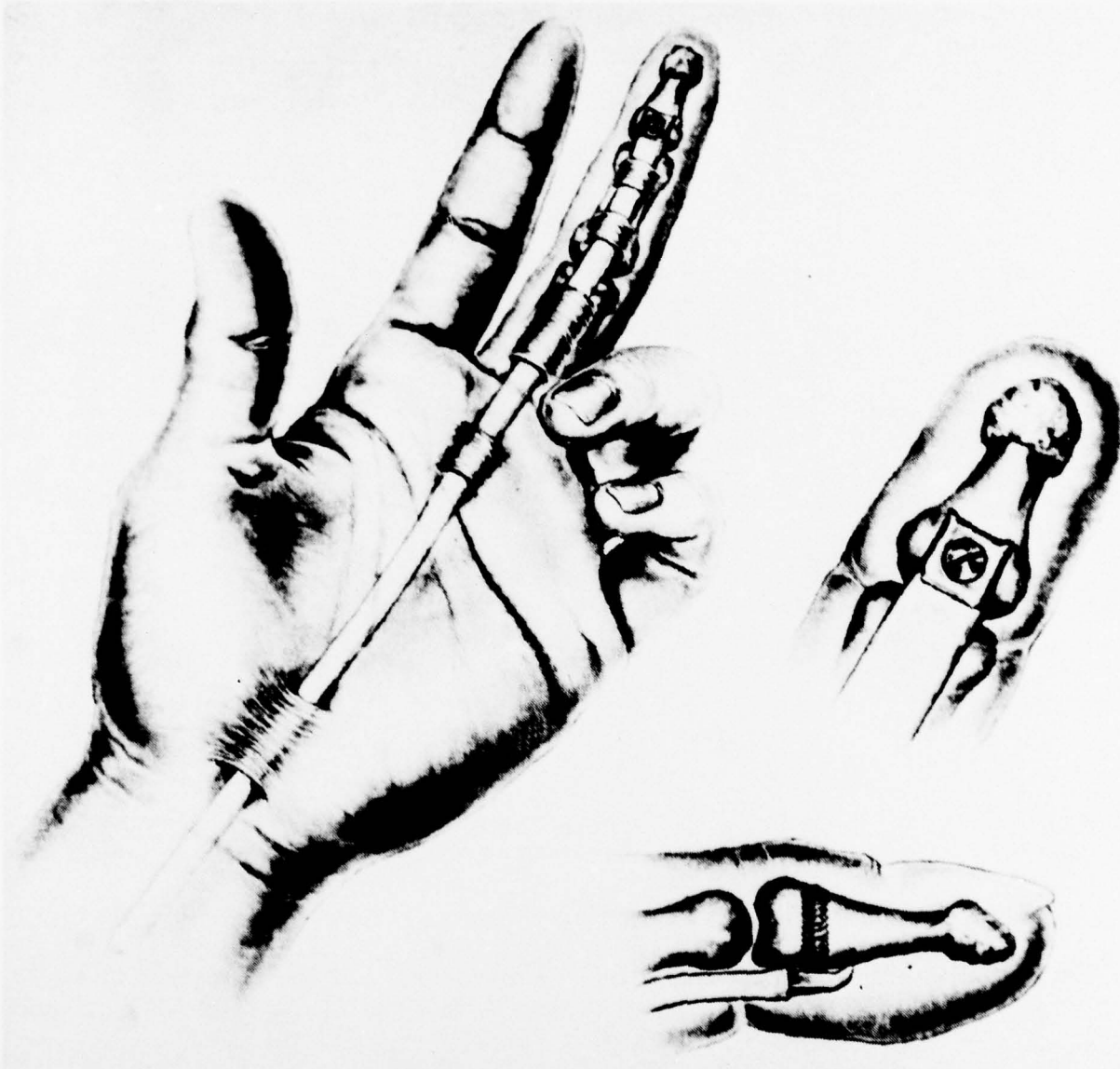
....indicated for use in the two-stage procedure developed by Dr. James
   M. Hunter for the reconstruction of flexor and extensor tendons in
   individuals having significant hand tendon injury.

....the only tendon implant with a distal end fixation system.

....another advancement toward an active tendon.

3rd & Mill Streets, P. O. Box 1, Bridgeport, Penna. 19405, U.S.A. — 215/277-6650

PRELIMINARY REPORT ON

THE RETINACULAR "PULLEY" SYSTEM

Prepared by:

James M. Hunter, M.D.

Naoyuki Ochiai, M.D.

Glenn A. Mackin, B.A.

Purpose: During surgery of the finger flexor tendons, the pulley system must be partially resected in some cases, and reconstructed in others. This experiment was designed to determine which parts of the pulley system may be resected, and which must be reconstructed, without losing effective range of motion of each joint.

Method: From some fresh human cadaver hands, fingers were resected at the carpometacarpal joint with both flexor tendons, the extensor tendon, and the pulley system intact. Two holes were drilled through the metacarpal bone vertically with respect to the saggital plane. The prepared fingers were fixed to a board with two bolts passed through the two holes in the metacarpal shaft. Wires were sutured to the flexor digitorum profundus (FDP) tendon and the extensor digitorum communis (EDC) tendon at the carpometacarpal joint level, respectively. The full range of motion of the distal interphalangeal joint, the proximal interphalangeal joint, and the metacarpophalangeal joint with intact pulley system was determined by pulling FDP with wire for its full excursion. (Note that the test parameter here is excursion only, and not the force exerted through FDP. The latter is properly the subject of an additional study in which the force exerted by the pulleys against tendon "bowstringing" is electronically measured.) A standard angle, the summation of angles of flexion for each joint, was measured at full range of motion and defined to be the 100% value. Then, utilizing various combinations of pulley resections, range of motion for each joint was measured, and the entire finger photographed. In each case, the excursion of FDP was kept constant at standard excursion. To support the finger, EDC was always pulled very slightly. After all pulleys were resected, new pulleys were reconstructed at various levels using brass wire passed through the shaft of each phalanx. The range of motion of each joint was then measured in the same manner, and percentage of maximum range of motion was calculated.
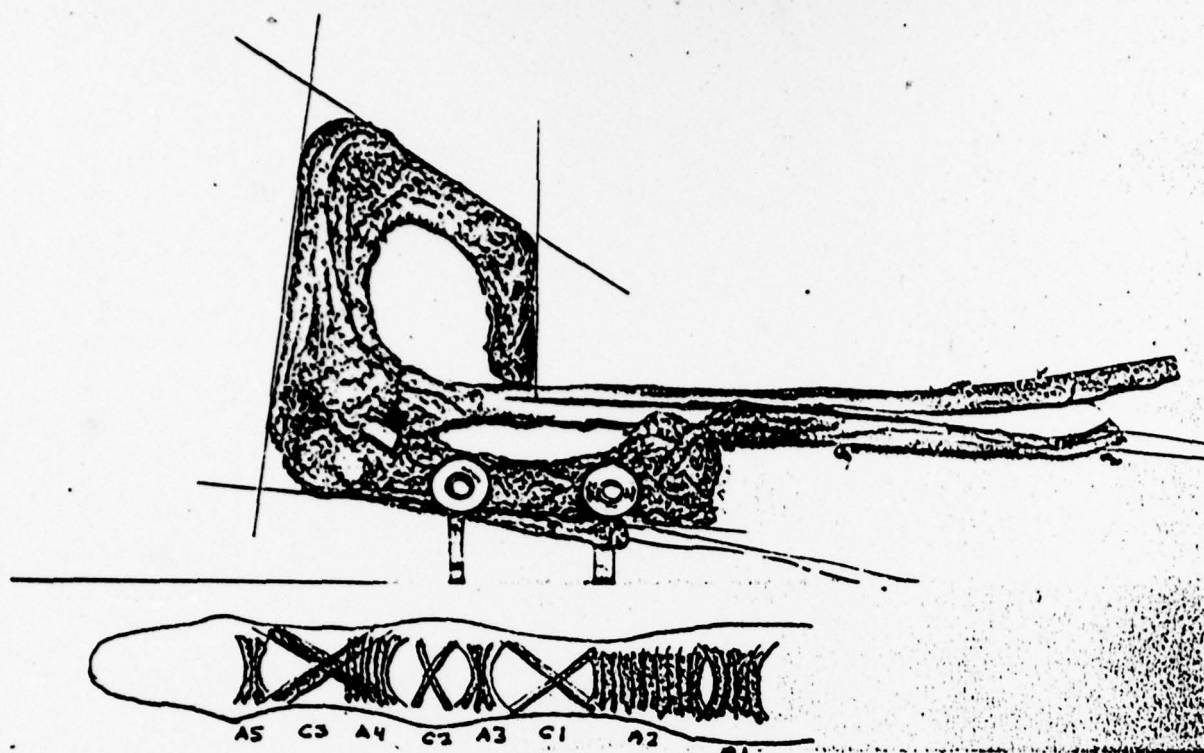
Figure 1: This shows the maximum range of motion for each joint with an intact retinacular "pulley" system. In this condition, total angle ranged from 250° to 285°. (100%, by definition)
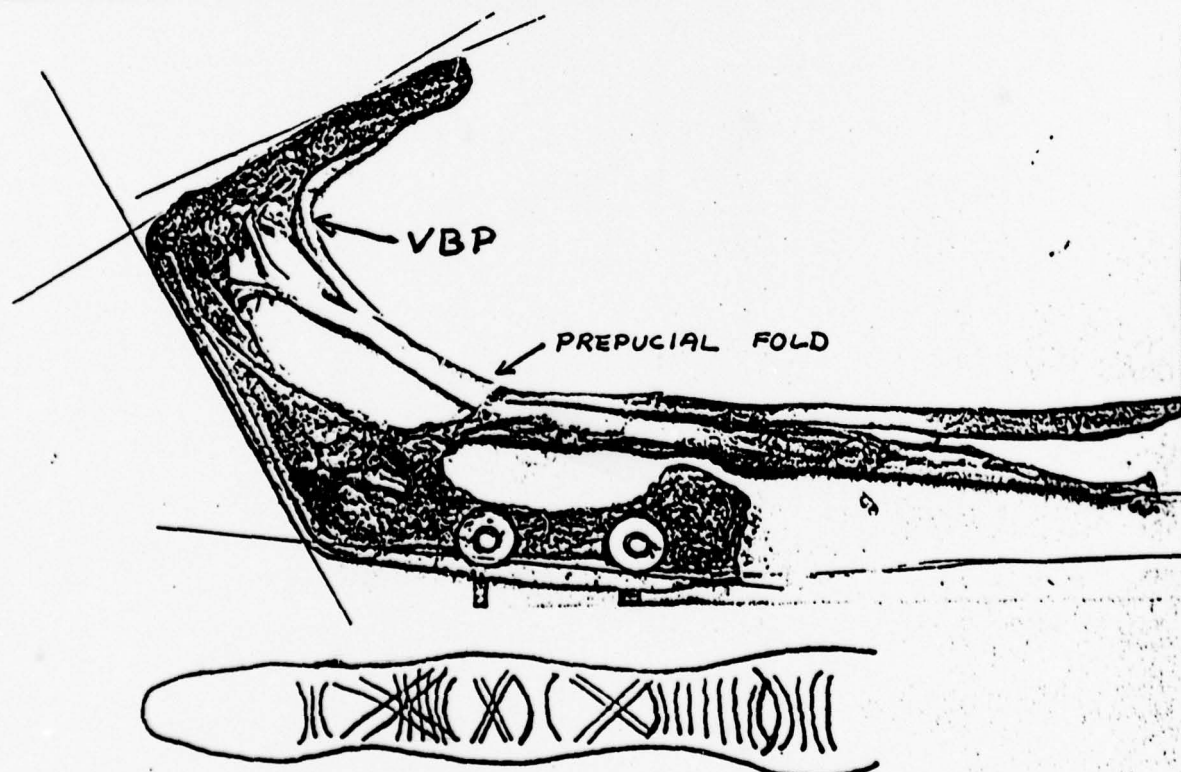

Figure 2: This shows range of motion for each joint when all pulleys have been resected. The total angle ranged from 144° to 189°. (56 to 66%). In this case, the prepucial fold acts as a pulley. The Vinculum Brevum Profundus (VBP) seems to prevent the transmission of pulling force to the distal phalanx. As shown, when pulleys are totally removed, pulling force is transmitted to the neck of the middle phalanx.

WHERE SHOULD PULLEYS BE RECONSTRUCTED?
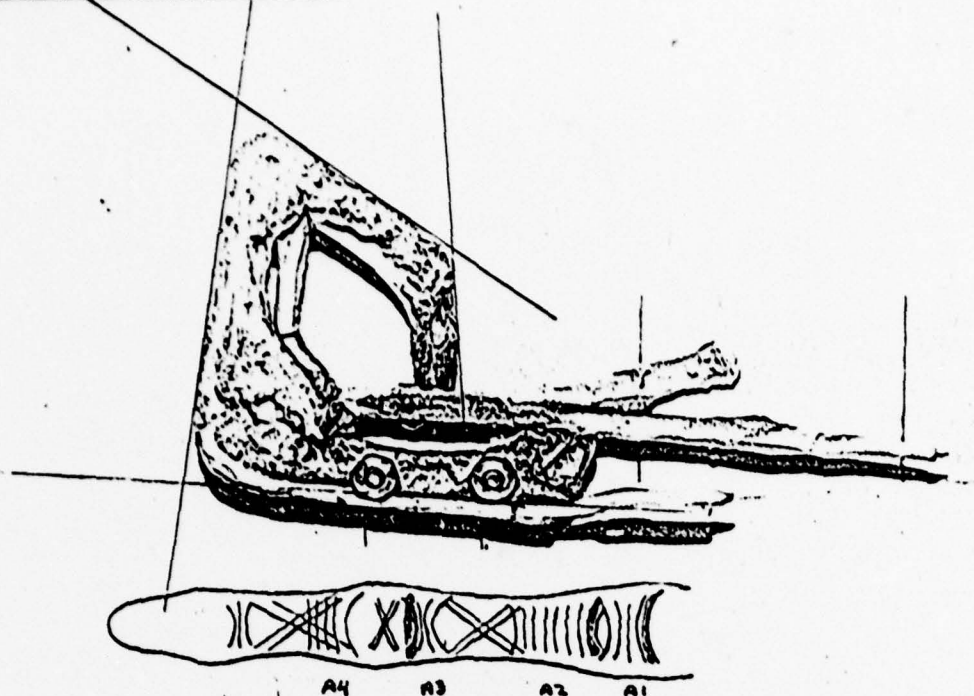
Figure 3: In this case, three pulleys were reconstructed with wire at the proximal ends of both the (annular) A1 and A2 pulleys, and at the base of the middle phalanx. The total angle became 262°. (101%, compared with intact system)
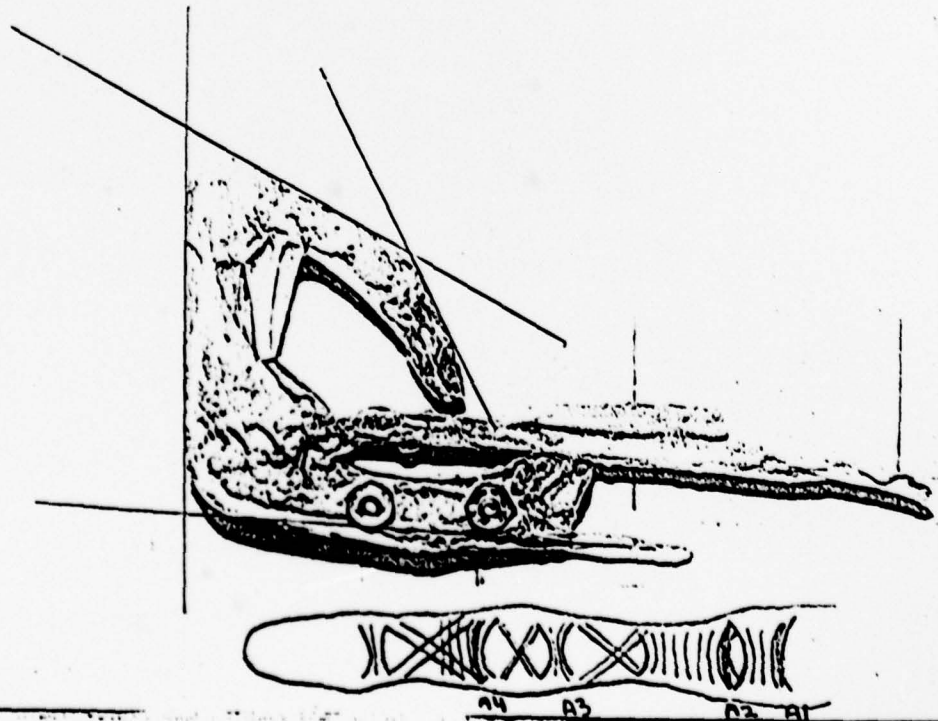

Figure 4: In this case, the distal pulley in Figure 3 was moved to the level of the proximal end of the A4 pulley. The total angle became 240°. (93%) Together, Figures 3 and 4 show that the nearer the pulley is located to the joint, the more effectively it works.
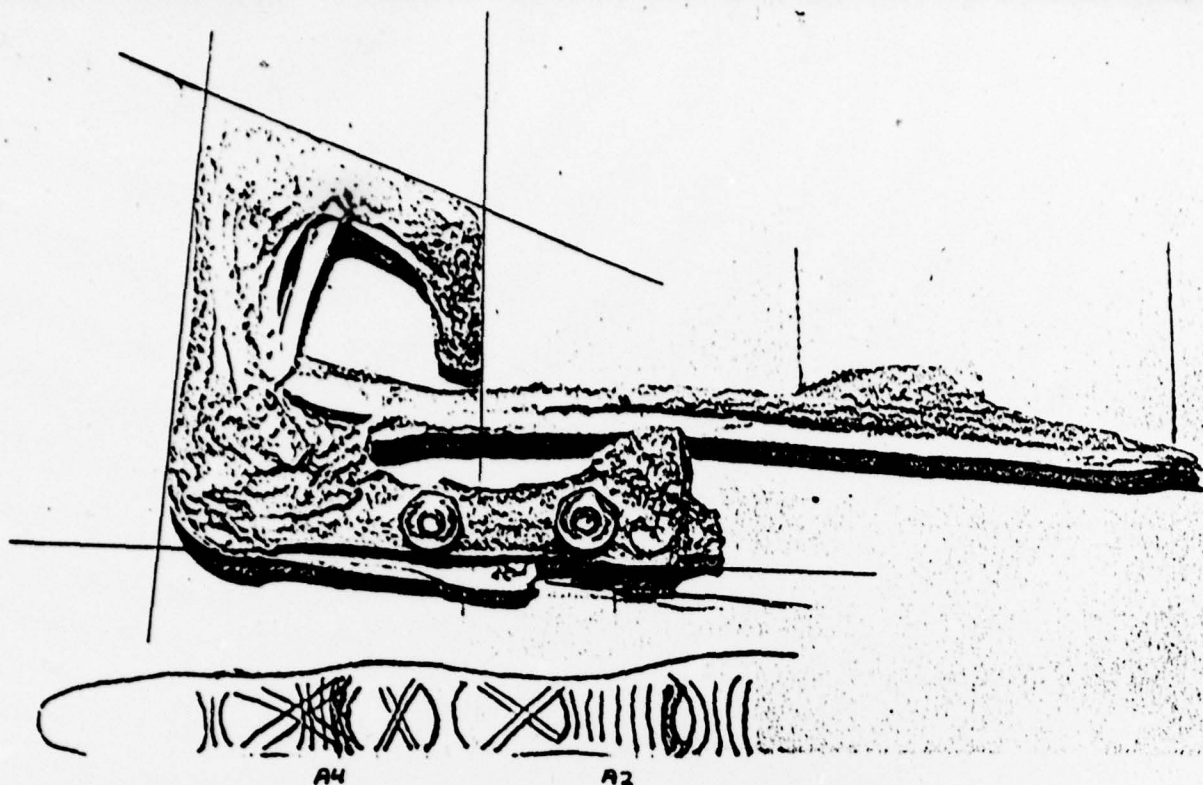
Figure 5: This shows that when two pulleys are reconstructed at the level of the proximal ends of the A2 and A4 pulleys, range of motion is 227° to 268°. (86% to 94%)

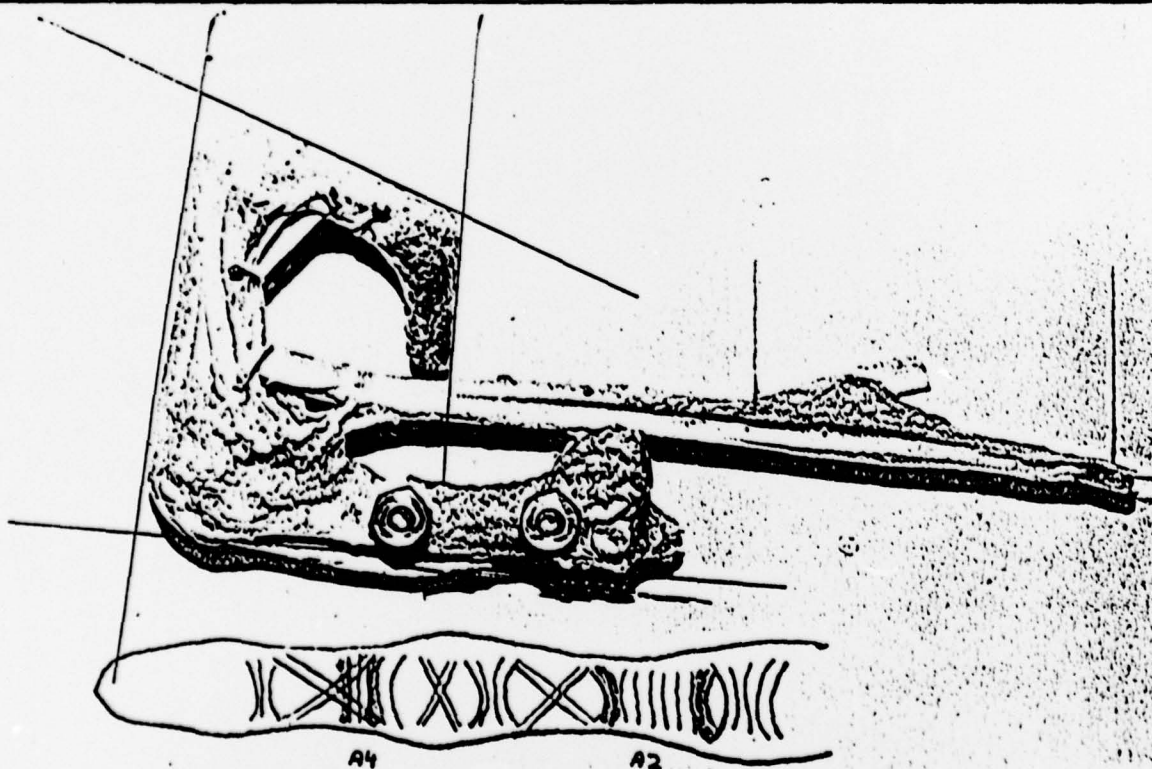

Figure 6: In this case, pulleys were reconstructed at both ends of the A2 and A4 locations. Total angle was 235° to 269°. (89% to 94%)
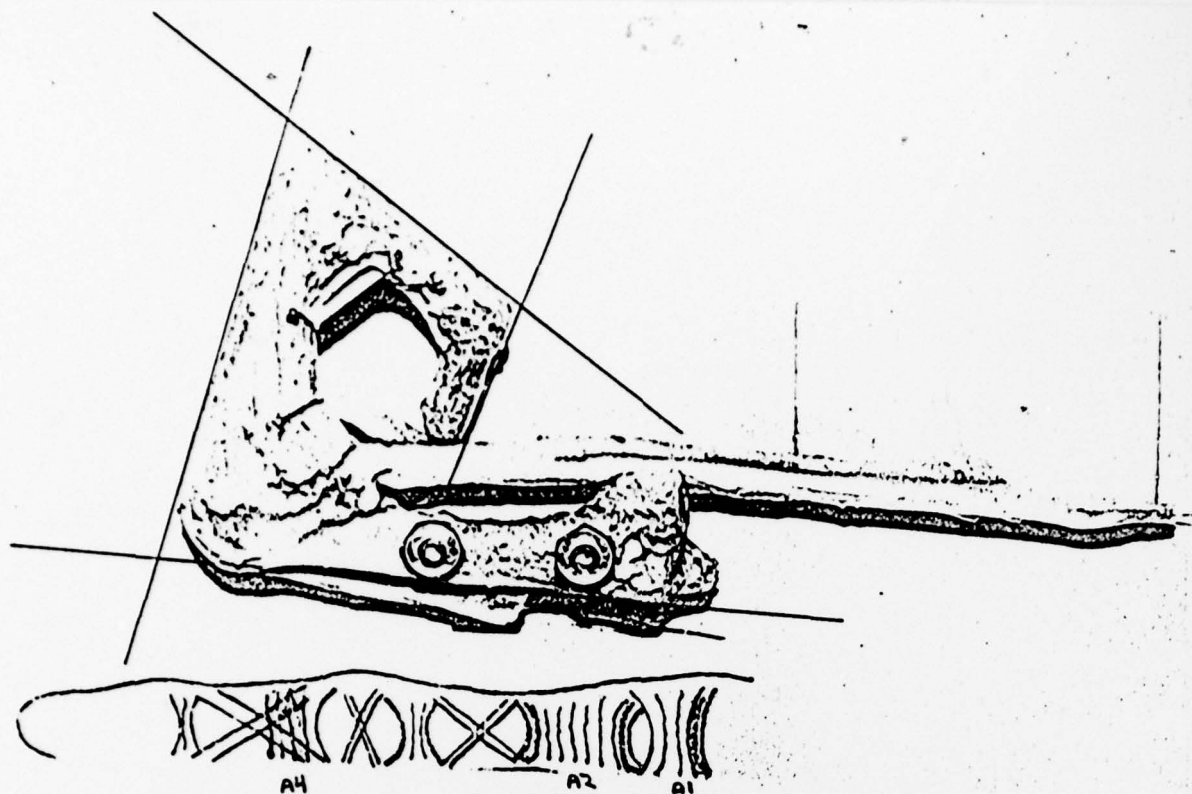
Figure 7: Here, a pulley was reconstructed at the level of the proximal end of A1, in addition to those reconstructed in the previous two figures. Total angle became 262° to 285°. (99% to 100%) Together, Figures 3 through 7 demonstrate that pulleys should be reconstructed at least at the bases of both the middle phalanges. If it is possible, another pulley should be reconstructed for A1, at the neck of the metacarpal bone. When this is done, range of motion is almost 100%.

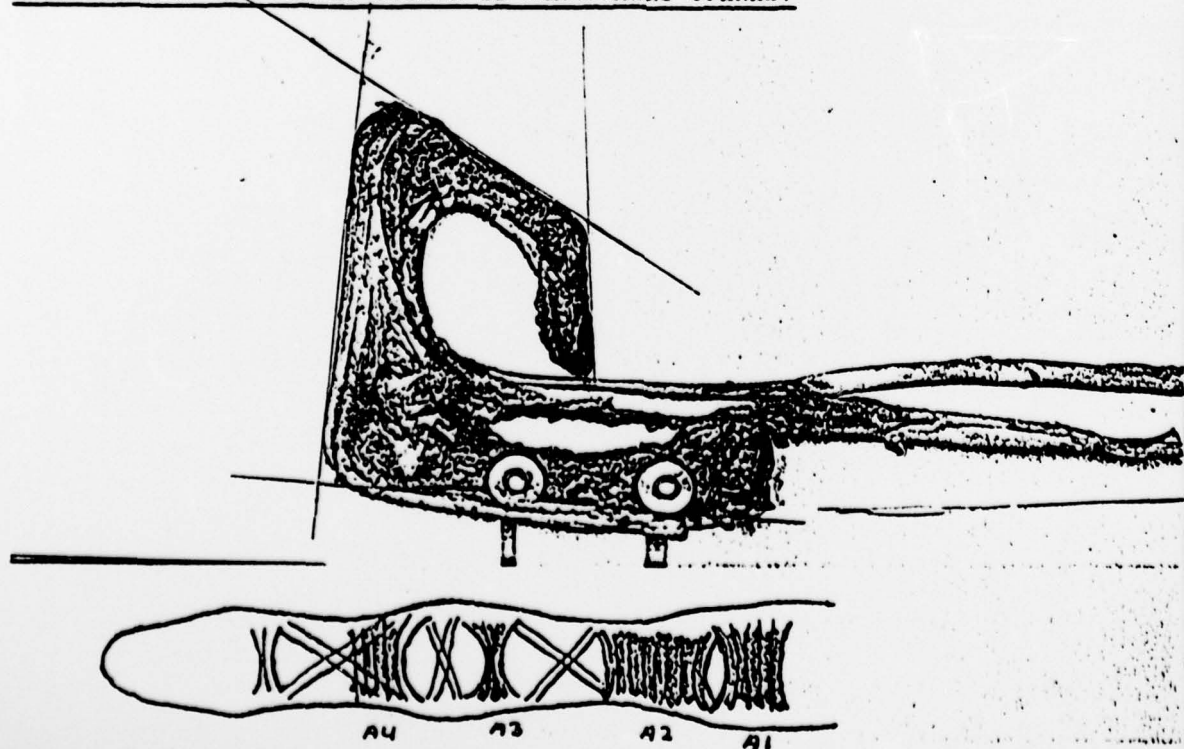WHERE SHOULD THE PULLEY SYSTEM BE SURGICALLY OPENED?

Figure 8: In this case, all three cruciform pulleys and the A5 pulley have been resected. No change in range of motion was observed. (100%)
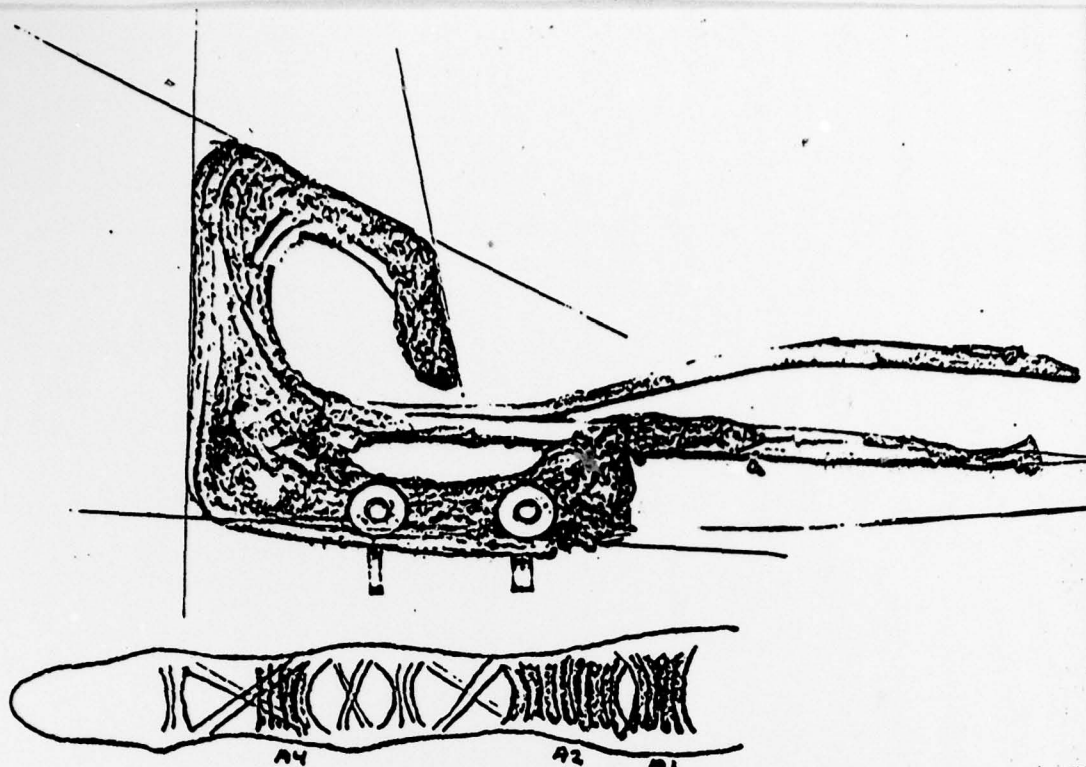
Figure 9: Compared with the previous figure, A3 has now been resected, leaving only A1, A2, and A4 pulleys. Total angle was 249° to 255°. (96%)
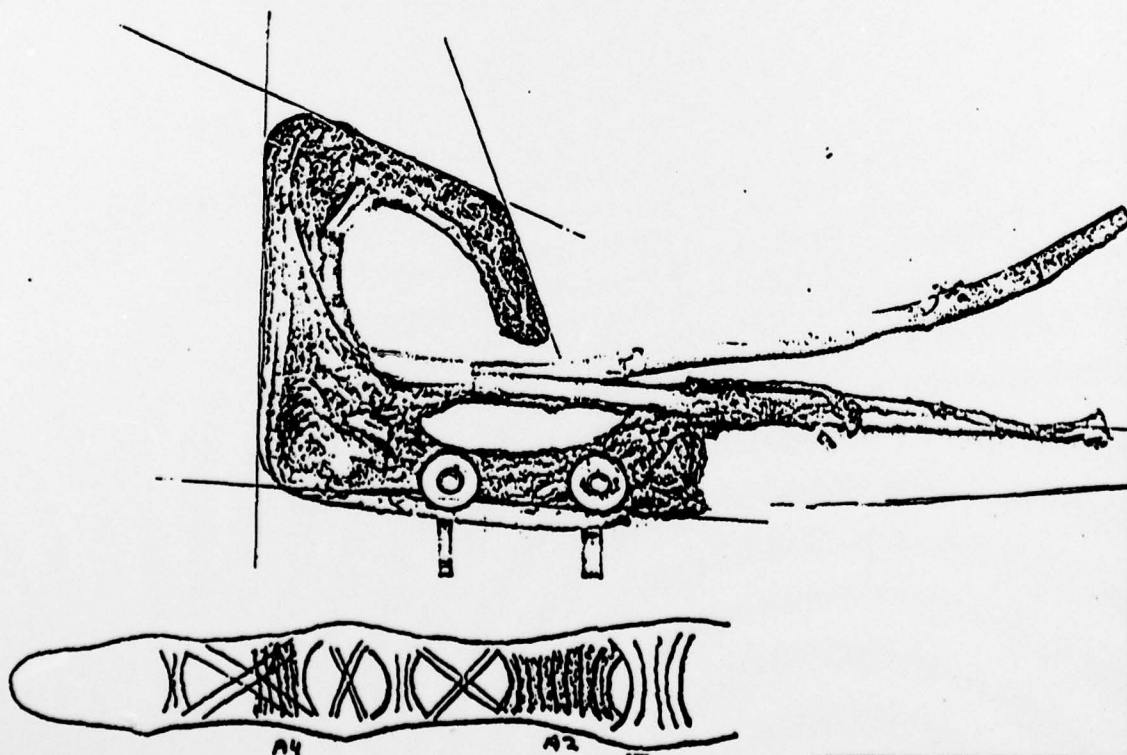

Figure 10: Compared with the previous figure, A1 has now been resected, leaving only A2 and A4 pulleys. Total angle was 243°. (93%)
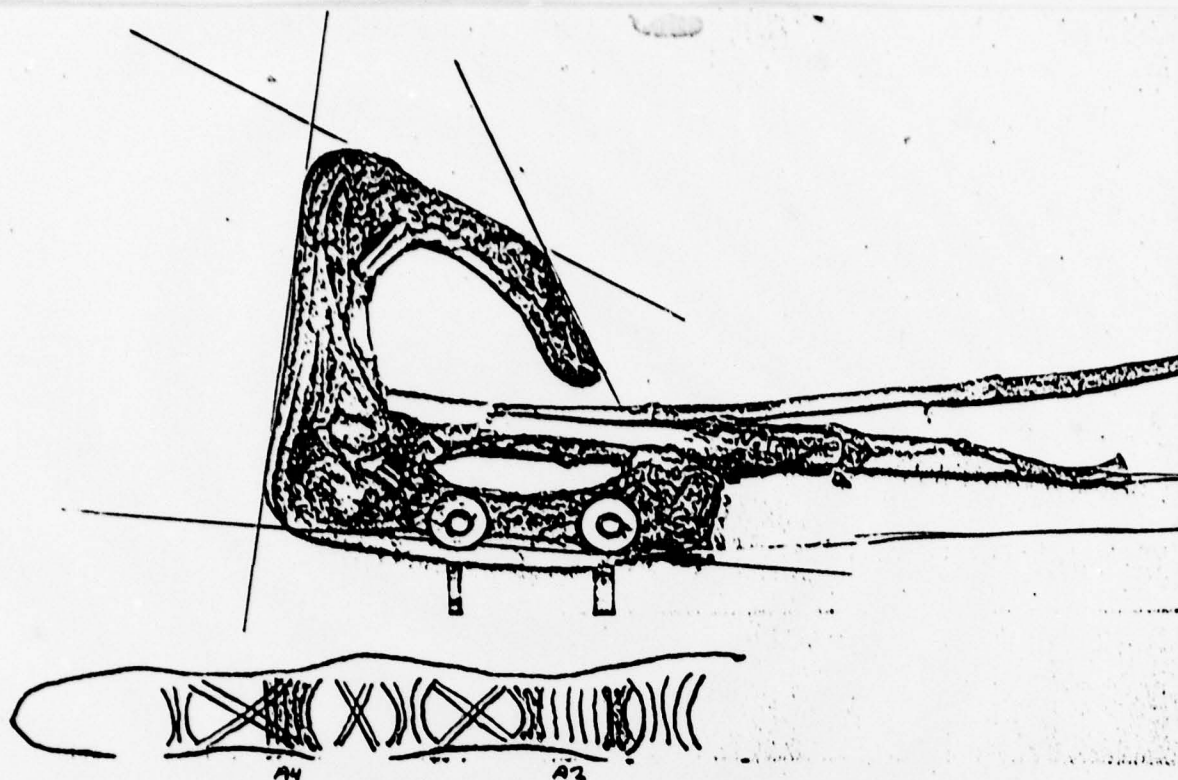
Figure 11: Compared with the previous figure, the middle part of A2 pulley has now been resected, leaving only the A4 pulley and the proximal and distal ends of the A2 pulley. Total angle was 241° (91%), which does not constitute a significant difference from the situation in Figure 10.
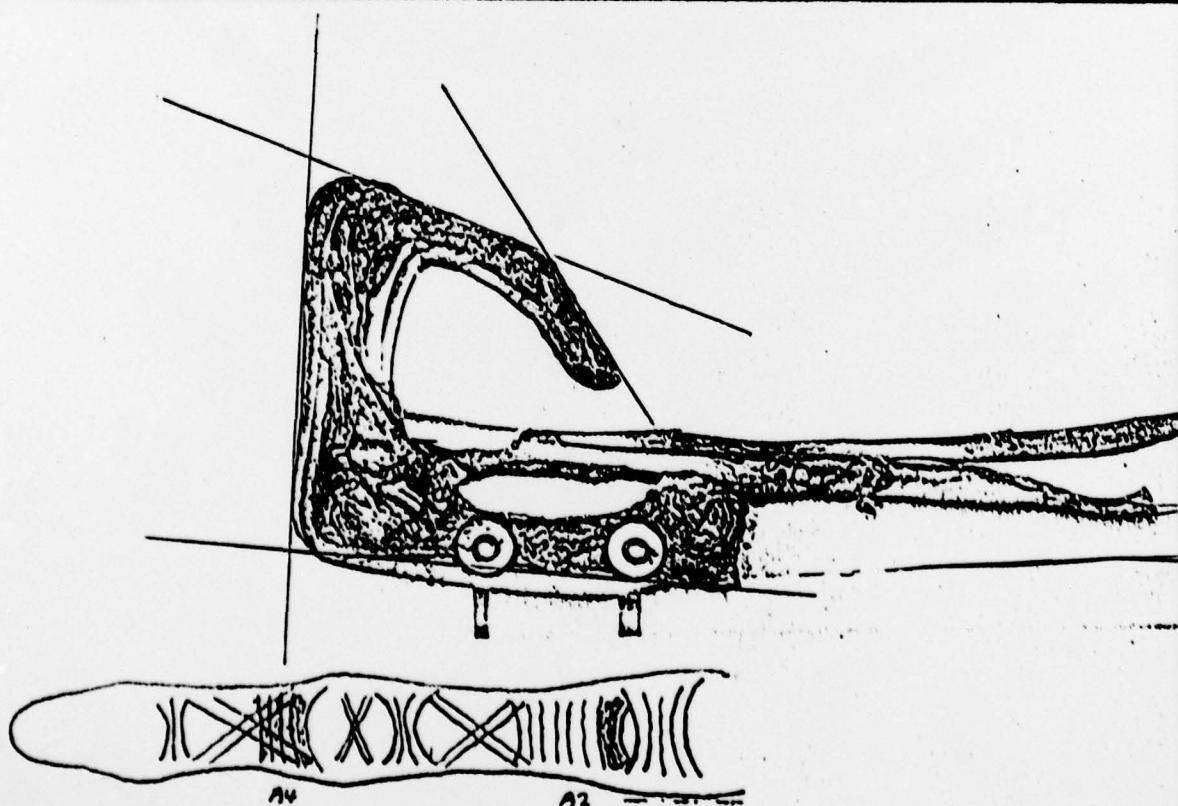

Figure 12: Compared with the previous figure, the distal part of A2 pulley has now been resected, leaving only the A4 pulley and the proximal end of the A2 pulley. Total angle was 234° (89%), which does not constitute a significant difference from the situations in either Figure 10 or 11.
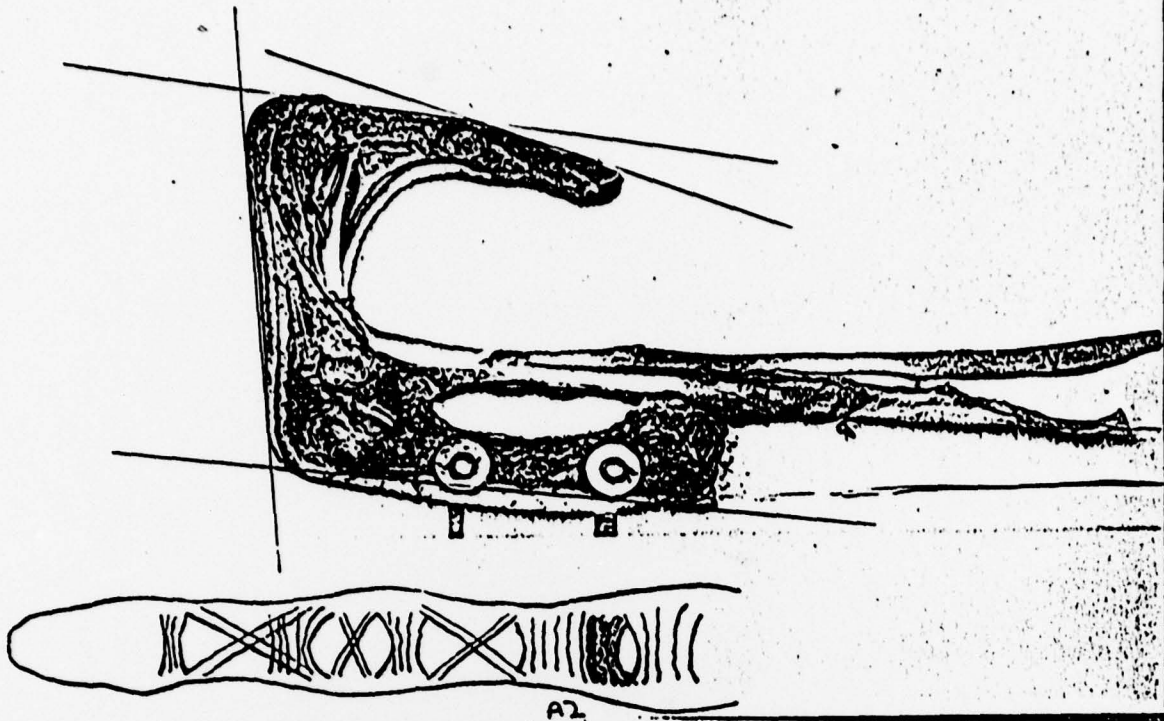
Figure 13: Only the proximal part of the A2 pulley has been left intact in this figure. Total angle decreased to 194°. (73%)

Slides 8 through 13 demonstrate that, in practice, the A1, A2, and A4 pulleys should be left intact if possible. At least the A4 pulley and the proximal part of the A2 pulley should be left intact. Surgically, this means that it is preferable to open the digital sheath at the level of the cruciform pulleys and its membranous part.

PHOTOGRAPHIC STUDY OF A PASSIVE TENDON IMPLANT

WITH SINTERED TITANIUM PLUG

SHOWING BIOCOMPATABILITY AND BONE INGROWTH

AFTER 10 MONTHS IN CHIMPANZEE FINGER

Prepared by:

James M. Hunter, M.D.

Naoyuki Ochiai, M.D.

Glenn A. Mackin, B.A.

SUMMARY: A sintered titanium plug, implanted for ten months in a chimpanzee's ring finger, was sectioned and photographed under a light microscope. The resultant demonstration of biocompatability and firm bone ingrowth reaffirms the sintered titanium plug design as a valuable end device for the projected active tendon prosthesis.

SURGICAL HISTORY OF CHIMPANZEE FINGER AND PASSIVE IMPLANT USED:

6/24/77: The distal end of a failed active tendon implant was found unattached at the level of the middle of the proximal phalanx in the right ring finger of chimpanzee "Max". There was marked synovitis distally, and good sheath around the implant shaft. (The A1 and A2 annular pulleys had previously been reconstructed on 8/10/76.) The proximal end of the implant was found firmly anastomosed with the sublimis muscle belly, which was then excised and blocked. At this point, the implant was removed. A 3.0 mm passive tendon implant with a 4.0 mm sintered titanium plug was then attached to the proximal third of the middle phalanx and passed into the sheath.

8/10/77: Some fluid was found in the sheath, but this was considered minimal inflammation after the active tendon failure. Breaking tension of the passive implant's distal attachment was measured to be 18.5 lbs. In breaking, the implant tape pulled through the titanium plug, which remained undisturbed in the middle phalanx, indicating good bone ingrowth. The proximal interphalangeal joint was disarticulated, thereby removing the passive implant from the finger. Next, a passive tendon implant with a 4.0 mm titanium plug was inserted obliquely into the distal third of the proximal phalanx. The tip of this implant protruded slightly on the dorsum. Fit was quite good, and the plug withstood light tension.

6/9/78: Anterior to the plug-bone interface was an area of soft, old granulation tissue. The mild sheath inflammation was therefore probably not caused by the present titanium plug. The distal third of the proximal phalanx, firmly attached to plug, was removed for study.

SPECIMEN PREPARATION: Gross sections of the sintered titanium plug embedded

in bone were made at a thickness of 5 microns. They were stained with

hematoxylin and eosin, but were not hardened with methacrylate. Photographs

of the sections were taken at various points around the plug under a

light microscope at 90x magnification.

FINDINGS: Copies of several photographs representative of the series are attached.

The sintered titanium plug, as indicated in the photographs, appears as an

opaque black convex mass at the edge of each photograph. A wide variety

of bone ingrowth patterns can be observed. Bone tissue has clearly grown

into the interstices of the sintered titanium plug during the ten month implant

period. Particularly noteworthy are the "tentacles" of bone tissue shown

"streaming" toward the plug. The most significant aspect of these photographs

is that the bone and titanium are consistently and solidly secured to one

another, with no evidence of inflammation at the interface. Considering the

inflammation already present in the tendon sheath due to prior implant

procedures, this demonstration of biocompatability at the bone-plug interface

is all the more striking. It provides further evidence for the sintered

titanium plug as a promising end device design for the new active tendon
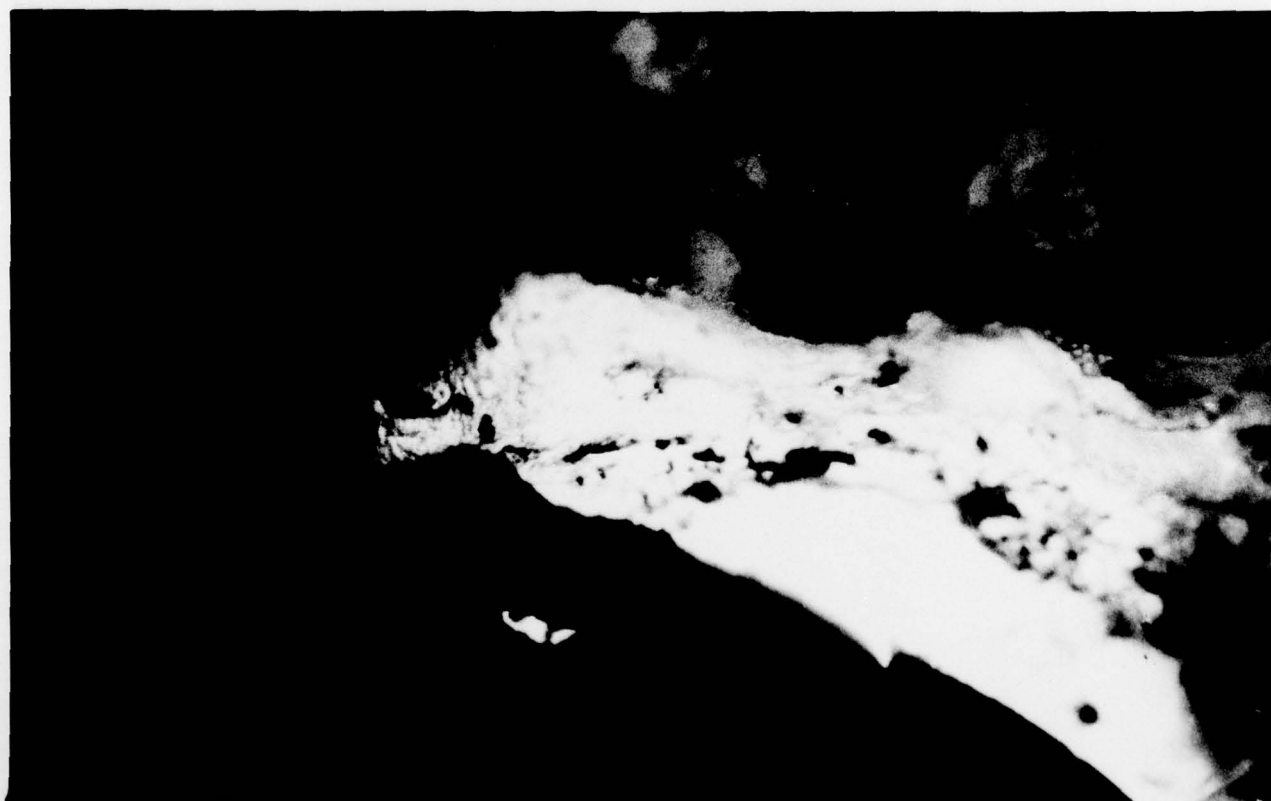
implant.
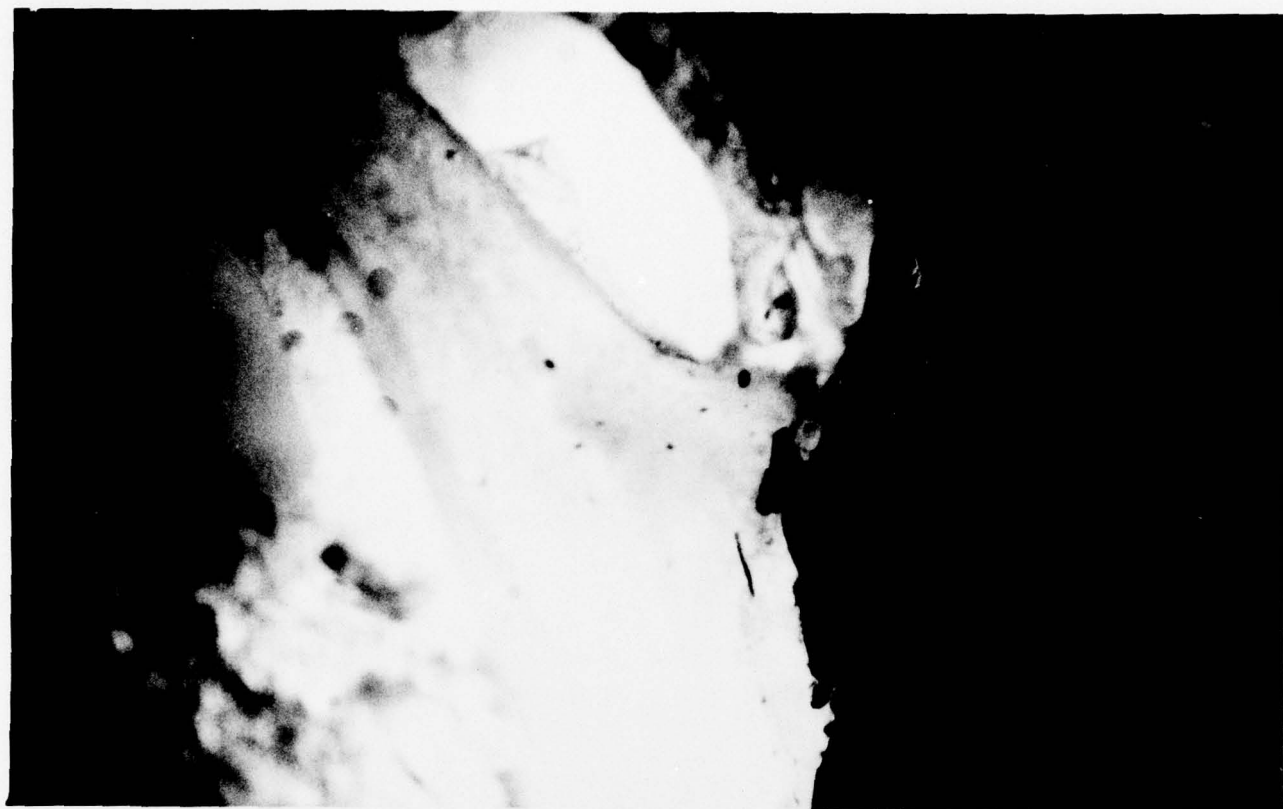
↑ SINTERED TITANIUM PLUG
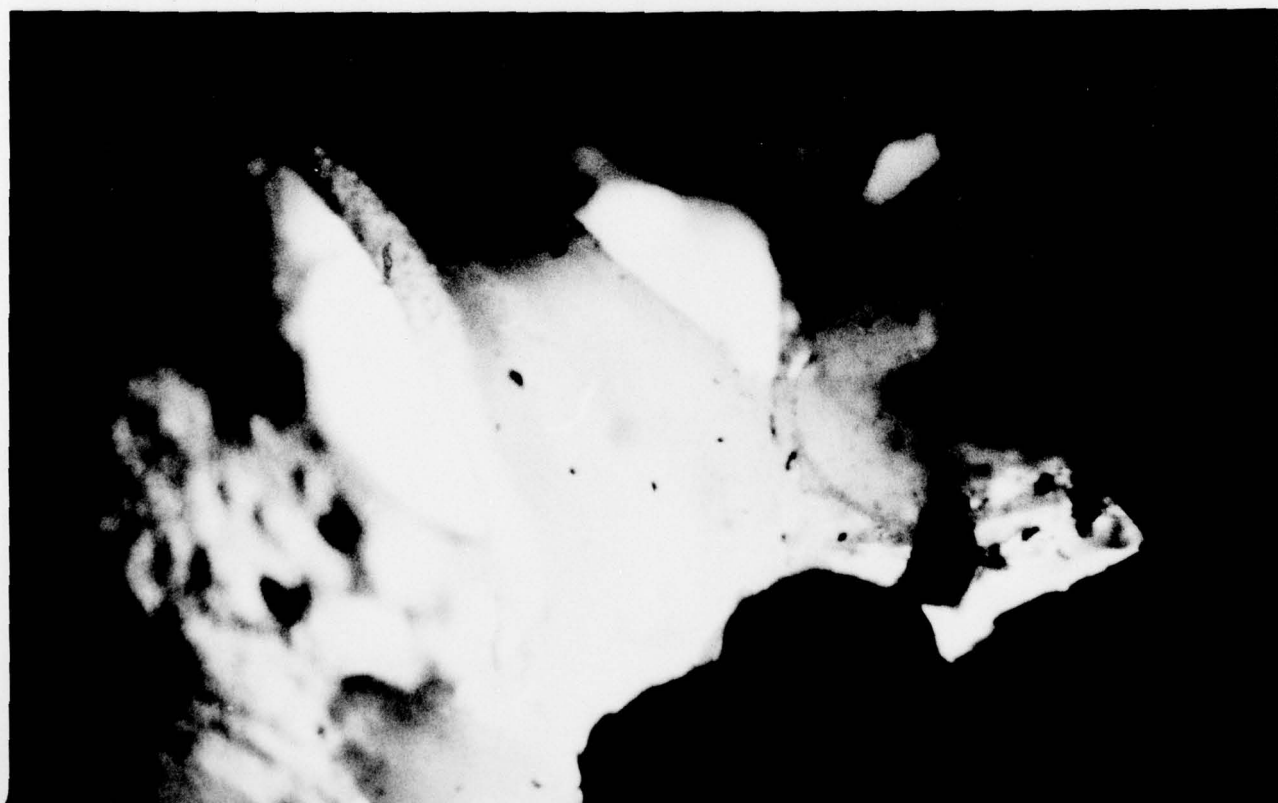
↑ SINTERED TITANIUM PLUG

SINT. TI. PLUG

SINTERED TITANIUM PLUG

RECENT PAPERS AND PRESENTATIONS ON RESEARCH WORK

JAMES M. HUNTER, M.D. (Chief Investigator):

Publications:

1. "A Study of Microvascularization of Human Finger Flexors,"
    The Journal of the Japanese Orthopaedic Association, Vol. 52,
    No. 5, May 1978. N. Miyaji, J.M. Hunter, and R.J. Merklin.
    pp. 687-694.

2. "A Consideration of the Pseudosheath Formed by Controlled Passive
    Artificial Tendon Prosthesis - Histological Structure and Fates,"
    The Journal of the Japanese Orthopaedic Association, Vol. 52,
    No. 5, May 1978. N. Miyaji, J.M. Hunter, and S.H. Jaeger.
    pp. 695-703.

3. "Vascular Anatomy of Flexor Tendons. Part I, Vincular System and
    Blood Supply of the Profundus Tendon in the Digital Sheath,"
    Journal of Hand Surgery (Accepted for publication, 1978).
    N. Ochiai, T. Matsui, N. Miyaji, R.J. Merklin, and J.M. Hunter.

4. "Vincula in No Man's Land," Jefferson Orthopaedic Journal, Vol. VII,
    No. I, 1978. J.M. Hunter, N. Ochiai, T. Matsui, R.J. Merklin,
    and G.A. Mackin. pp. 33-40.

5. Rehabilitation of the Hand. St. Louis: C. V. Mosby, 1978.
    J.M. Hunter, L.H. Schneider, E.J. Mackin, and J.A. Bell, editors.

Presentations (1978):

1. "Flexor Tendon Injury to the Hand" (April 15). Harvard Medical School
    and the Massachusetts General Hospital, Boston, Mass.

2. "Acute Flexor Tendon Injuries" (April 20), and "Flexor Tendon
    Reconstruction" (April 21). Sixth Annual Georgetown University
    Hand Symposium, Washington, D. C.

3. "Concerning Recent Lacerations of Tendons of the Hand and
    Intrinsic Vascularization," and "Methods of Staged Tendon
    Reconstruction and Current Progress on an Active Tendon Implant"
    (April 24). Brazilian Meeting of Plastic Surgeons, Sao Paolo, Brazil.

4. "Vascular Anatomy of Flexor Tendons: Update" (September 7).
    Tenth Annual Meeting of the Robert E. Carroll Hand Club, Cape Cod, Mass.

5. "Tendon Reconstruction Using Implants" (September 21). Symposium
    on Implant Surgery of Joints and Tendons of the Hand, American Society
    for Surgeons of the Hand, Grand Rapids, Mich.

JAMES M. HUNTER, M.D.

Presentations (continued):

6. "Vascular Implications of Flexor Tendon Injuries" (October 5).
   St. Luke's Hospital Medical Center, Phoenix, Ariz.

7. "A Microvascular Study of the Human Flexor Tendons in the Digital
   Fibrous Sheath - Normal Blood Vessel Arrangement in Tendons and
   the Effect of Injuries to Tendons and Vincula on Blood Supply"
   (October 15). SICOT '78, Kyoto, Japan. (Presented by T. Matsui, M.D.)

8. "Flexor Tendon Problems" (October 23). Symposium on Difficult Problems
   in Hand Surgery, American Society for Surgeons of the Hand,
   Indianapolis, Ind.

FRANK KO, PH.D. (Philadelphia College of Textiles and Science):

Presentations (1978):

1. "Viscoelastic Behavior of Fibers Under Physiological Conditions"
   (March 27). Joint Meeting of the American Physical Society and
   the Biophysical Society, Washington, D.C. (F. Ko, S. Winston, and
   D. Buchanan.

2. "Development of Soft Tissue Prostheses - Active Artificial Tendons"
   (May 10). The Fiber Society, Princeton, N. J. (F. Ko)

3. "Nonlinear Viscoelastic Behavior of Human and Canine Flexor Tendons
   in Simple Elongation" (September 1). The Third International Congress
   on Biorheology, San Diego, Calif.

REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER	2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE *(and Subtitle)* The Development and Application of a Tendon Prosthesis for the Early Functional Restoration of the Injured Hand		5. TYPE OF REPORT & PERIOD COVERED Annual Report 1 Sept 1977 to 30 Nov 1978
		6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s) James M. Hunter, M. D. John J. Konikoff, Ph. D. Glenn A. Mackin, B. A.		8. CONTRACT OR GRANT NUMBER(s) DAMD 17-76-C-6036
9. PERFORMING ORGANIZATION NAME AND ADDRESS Jefferson Medical College Philadelphia, Pennsylvania 19107		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS 62772A 3S762772A815.00.001
11. CONTROLLING OFFICE NAME AND ADDRESS US Army Medical Research and Development Command Fort Detrick, Frederick, Maryland 21701		12. REPORT DATE November 1978
		13. NUMBER OF PAGES 38 pages
14. MONITORING AGENCY NAME & ADDRESS*(if different from Controlling Office)*		15. SECURITY CLASS. *(of this report)* Unclassified
		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT *(of this Report)* Approved for public release; distribution unlimited.		
17. DISTRIBUTION STATEMENT *(of the abstract entered in Block 20, if different from Report)*		
18. SUPPLEMENTARY NOTES		

19. KEY WORDS *(Continue on reverse side if necessary and identify by block number)*

1.	Hand Surgery	5.	Dacron
2.	Tendon	6.	Kevlar
3.	Prosthesis (or Prosthetic Devices)	7.	Titanium
4.	Finger	8.	Silicone

20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)*

The report details progress made toward an active tendon prosthesis for the reconstruction of severely injured digital flexor tendon systems. Secure distal prosthesis attachment to bone may be either by bone ingrowth into a sintered titanium plug, or by screw fixation of a high carbon steel plate. High strength polyester fiber (Dacron) is the prosthesis shaft material of choice despite equally favorable biocompatability properties of Dacron and aramic fiber (Kevlar). Impact energy of rapid muscle contraction will be absorbed by braided shaft design continuous with a proximal soft loop. The

DD FORM 1473 EDITION OF 1 NOV 65 IS OBSOLETE
1 JAN 73

method for coating the prosthesis shaft with silicone rubber will be pressure molding, not dip coating. Studies of the strength, microcirculation, and biomechanics of the digital flexor tendon system were conducted using human cadaver hands.